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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/802,358	03/09/01	ACH	R 10971722-2

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EXAMINER	
CHAKRABARTI,A	
ART UNIT	**PAPER NUMBER**
1655	4

DATE MAILED: 11/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/802,358	Ach
Examiner	**Art Unit**
Arun Chakrabarti	1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Aug 3, 2001 .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 17-20 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 17-20 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 17-20, drawn to ribonucleotides, classified in class 536, subclass 22.1+.

II. Claims 21-23, drawn to method of nucleic acid hybridization, classified in class 435, subclass 6.

2. The inventions are distinct, each from the other because of the following reasons: Inventions of Group I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the ribonucleotides product of Group I can be used to detect the target nucleic acid by hybridization of Group II or can be used to make protein or can be used to make antisense nucleic acid for gene therapy.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Gordon Stewart on July 26, 2001, a provisional election was made with traverse to prosecute the invention of Group I, claims 17-20. Affirmation of this election must be made by applicant in replying to this Office action. Claims

21-23 are withdrawn from further consideration by the examiner, 37 CAR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 17-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for prokaryotic bacteria E. Coli poly(A)polymerase, does not reasonably provide enablement for any prokaryotic poly(A)polymerase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 17- 20 are rejected under 35 U.S.C. 103 (a) over Life Technologies Catalog (Page 13-11, 1995-1996) in view of Urdea (U.S. Patent 5,380,833) (January 10, 1995) further in view of Matthews et al. (Analytical Biochemistry, (1988), Vol. 169, pages 1-25).

Life Technologies catalog teach a kit for use in end-labelling ribonucleic acids with labeled ribonucleotides, the kit comprising :

a labeled ribonucleotide; and a prokaryotic poly(A) polymerase isolated from E. Coli (Page 13-11, polyA polymerase Section).

Life Technologies catalog do not teach a non-radioactively and fluorescently labeled ribonucleotide.

Urdea teaches a non-radioactively and fluorescently labeled ribonucleotide (Column 7, line 63 to column 9, line 13).

Life Technologies catalog do not teach a non-radioactively labeled ribonucleotide CTP or UTP analog.

Urdea teaches a non-radioactively labeled ribonucleotide CTP or UTP analog (Column 9, lines 45-50).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the non-radioactively and fluorescently labeled ribonucleotide of Urdea into the method of end-labelling ribonucleic acids with labeled ribonucleotides and a prokaryotic poly(A) polymerase isolated from E. Coli of Life Technologies , since Urdea state, "The method finds use in diagnosis of disease, genetic monitoring, and

analysis of nucleic acid mixtures (Abstract, last sentence)." By employing scientific reasoning, an ordinary artisan would have combined and substituted the non-radioactively and fluorescently labeled ribonucleotide of Urdea into the method of end-labelling ribonucleic acids with labeled ribonucleotides and a prokaryotic poly(A) polymerase isolated from E. Coli of Life Technologies to improve the non-hazardous detection (by non-radioactive label) of target molecules. An ordinary practitioner would have been motivated to combine and substitute the non-radioactively and fluorescently labeled ribonucleotide of Urdea into the method of end-labelling ribonucleic acids with labeled ribonucleotides and a prokaryotic poly(A) polymerase isolated from E. Coli of Life Technologies , in order to achieve the express advantages noted by Urdea, of a method which finds use in diagnosis of disease, genetic monitoring, and analysis of nucleic acid mixtures.

Life Technologies Catalog in view of Urdea do not teach the motivation to use fluorescent labels as alternatives of the radioisotopic labels.

Matthews et al. teach the motivation to use fluorescent labels as alternatives of the radioisotopic labels.(Page 5, Column 2, Labels Section and Page 8, Column 1, line 8 to Column 2, line 4).

It would have been *further prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the motivation to use non-radioactively and fluorescently labeled ribonucleotide of Matthews et al. into the method of end-labelling ribonucleic acids with labeled ribonucleotides and a prokaryotic poly(A) polymerase

isolated from E. Coli of Life Technologies in view of Urdea, since Matthews et al. state, "Most attention has focused on alternatives to radioisotopic labels because of the associated problems of safety, stability, and waste disposal. (Page 5, Column 2, label section, lines 3-7)." By employing scientific reasoning, an ordinary artisan would have combined and substituted the motivation to use the equivalent non-radioactively and fluorescently labeled ribonucleotide of Matthews et al. into the method of end-labelling ribonucleic acids with labeled ribonucleotides and a prokaryotic poly(A) polymerase isolated from E. Coli of Life Technologies in view of Urdea to improve the non-hazardous detection (by non-radioactive label) of target molecules. An ordinary practitioner would have been motivated to combine and substitute the motivation to use non-radioactively and fluorescently labeled ribonucleotide of Matthews et al. into the method of end-labelling ribonucleic acids with labeled ribonucleotides and a prokaryotic poly(A) polymerase isolated from E. Coli of Life Technologies in view of Urdea , in order to achieve the express advantages noted by Matthews et al., of a method which focused on alternatives to radioisotopic labels because of the associated problems of safety, stability, and waste disposal.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Arun kr. Chakrabarti

Arun Chakrabarti,

Patent Examiner,

November 5, 2001